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# Comprehensive Geriatric Assessment for community-dwelling, high-risk, frail, older people (Protocol)

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[Intervention Protocol]

# Comprehensive Geriatric Assessment for community-dwelling, high-risk, frail, older people

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## ABSTRACT

This is a protocol for a Cochrane Review (Intervention). The objectives are as follows:

To assess the effectiveness of Comprehensive Geriatric Assessment (CGA) in community-dwelling, high-risk, frail, older adults.

## BACKGROUND

We live in an ageing world. The 20$^{th}$ century has seen an unprecedented gain of 30 years life expectancy in European and North American older people (Christensen 2009), and is mirrored by rapid population ageing in low- and middle-income countries (Smith 2003). This increased longevity is one of the greatest achievements of modern times, but it also poses significant challenges for provision of appropriate health care in a suitable environment to greater numbers of older people. High-income nations are now spending an increasing amount of gross domestic product (GDP) on health care (McCarthy 2015). As life expectancy increases, an age-attuned approach to assessment is becoming increasingly relevant to primary and secondary care (O'Neill 2011).

### Description of the condition

The population of interest in this Cochrane Review is community-dwelling older people at risk of functional decline, hospital admission or admission to residential care.

Currently around 4% of older people in Europe live in nursing homes (Rolland 2011), while 9 million people live in nursing homes in the United States alone (Harris-Kojetin 2016). The numbers of people requiring residential care will increase markedly in the coming years, with projections suggesting that admissions to nursing homes will rise by 127% and 111% in Germany and the UK respectively between the years 2000 and 2050 (Comas-Herrera 2003). Healthcare strategies for older people that are aimed at preventing disability and morbidity and averting the need for admission to residential care are therefore crucial (Colón-Emeric 2014). While most older people live independent healthy lives, longevity also brings an increased risk of adverse outcomes. We will therefore restrict this systematic review to patients who are community-dwelling and aged 65 years or more at the time of the study.

We will use frailty, a common clinical syndrome in older adults, which is characterised by decline in several physiological systems and collectively results in a vulnerability to sudden health state changes triggered by relatively minor stressor events (Clegg 2011), to define those 'at risk' of adverse outcomes.

### Description of the intervention

Comprehensive Geriatric Assessment (CGA) is one of the pillars of age-attuned care. It is defined as a "multidimensional interdisciplinary diagnostic process focused on determining a frail older person's medical, psychological and functional capability in order to develop a coordinated and integrated plan for treatment and long term follow up" (Ellis 2011). Thus CGA is not limited simply to assessment, but also directs a holistic management plan for the older person, which leads to tangible interventions.

These interventions are tailored to the specific needs of the patient and can involve the full spectrum of the multidisciplinary team, including specialist nurses, physiotherapy, occupational therapy, speech and language therapy, psychology and social work.

### How the intervention might work

There is established evidence from a previous Cochrane Review that, when delivered to acutely unwell older people, CGA reduces the likelihood of subsequent death and disability (Ellis 2011). However, the setting in which CGA was delivered and acted upon is also key, with benefits seen only on wards specialising in the care of older people (Ellis 2011). Delivery of CGA by a healthcare professional with an expertise in geriatric medicine is now considered central to acute in-hospital care of the older person (Scanlan 2005).

However, while care of the older person already comprises a large proportion of acute hospital activity, further future demographic shifts dictate that community-based interventions that reduce the need for hospitalisation will be increasingly important. Additionally, when older people present to the acute hospital, they have often already reached a point of significant functional decline (Isaia 2010). They also more commonly present with an exacerbation of a pre-existing chronic disease than with a de novo illness (Martin 2004), so targeted intervention at an earlier stage in disease trajectory could positively impact on this acquired disability, as well as reduce healthcare utilisation in tertiary facilities.

The acute hospital environment is increasingly recognised as an inappropriate setting for the care of frail older people. Hospital admission is associated with delirium (Ryan 2013), increased risk of falls (Rapp 2016), cognitive decline (Mathews 2014) and functional decline (Arnau 2016), independent of acute illness severity. While a previous Cochrane Review has demonstrated the significant impact of CGA once the older person is hospitalised (Ellis 2011), community-based CGA could impact significantly on healthcare delivery by averting acute hospital admissions, as well as giving older people access to timely specialist assessment in order to reduce the risk of functional decline and optimise medical care prior to the onset of acute illness.

There is also a likely benefit to be gleaned by seeing the older person in their own home, where one can readily assess how they interact with their own usual environment and issues, such as environmental hazards or falls risks, are more likely to be highlighted to the healthcare provider (Sahlen 2008). It also facilitates specialist review for frail older people with significant disability who would otherwise be unable to attend outpatient clinic appointments.

However, CGA is a finite resource and particularly when delivered in a community setting will need to be targeted at appropriate cohorts of patients in order for it to be practical and feasible. Identification of older people who would derive most benefit from such an intervention is therefore crucial. CGA may be particularly beneficial in older people with frailty, given their increased risk of poor health outcomes (Romero-Ortuno 2015).

### Why it is important to do this review

Demonstration of the benefits of a structured intervention targeted at older people prior to hospitalisation would be extremely valuable and would have significant impact on the organisation of medical services for older adults. While there is some evidence to date that community-based interventions targeted at older people are beneficial, as yet there has been no comprehensive review in this area (Ploeg 2005; Beswick 2008). Thus the aim of this Cochrane Review is to establish whether CGA, delivered in a community setting and at an earlier stage than at the point of admission to the acute hospital, would impact positively on healthcare utilisation, nursing home admission and mortality longitudinally in older people at risk of functional decline.

Policy makers may be concerned about the cost involved in provision of CGA to a wide population of community-dwelling older people. While initial evidence suggests that targeted interventions such as this are cost-effective (Counsell 2009), it is important to test this in a systematic review.

## OBJECTIVES

To assess the effectiveness of Comprehensive Geriatric Assessment (CGA) in community-dwelling, high-risk, frail, older adults.

## METHODS

### Criteria for considering studies for this review

### Types of studies

We will include individual and clustered randomised trials that compare intervention to usual care. Initial review of the literature suggests there will be a sufficient number of randomised trials for analysis.

Usual care is defined as the current standard care received by frail older people where the study is carried out. This may be unstructured and heterogenous between studies, but is likely to involve usual care by the general practitioner (GP) or family doctor in the community, with CGA provided only when the older person has been admitted the acute hospital or when they are referred by their GP to a Geriatric Medicine clinic with issues such as functional decline, cognitive decline, falls etc.

We will include full-text studies, conference abstracts and unpublished data. The minimum follow-up period for included studies will be six months, as this is the minimum amount of time until impact outcomes, such as nursing home admission, should be assessed. The intervention should be delivered in a community setting (participant's own home or primary care).

We will exclude the following types of studies.

- Studies that focus solely on a particular disease or syndrome, e.g. chronic disease, falls, stroke.
- Studies of interventions after discharge from hospital.
- Studies designed to test hospital avoidance in exacerbations of chronic conditions.
- Studies that involve participants who are not community-dwelling.

### Types of participants

We will include participants aged ≥ 65 years who satisfy each of the following criteria:

- Community dwelling.
- Not acutely unwell i.e. not currently an inpatient in an acute hospital and not presenting (to an emergency department or GP) for unscheduled care.
- Identified as at risk of institutionalisation or defined as frail.

Community dwelling is defined as living outside of an environment where 24-hour nursing care is provided onsite. This encompasses participants living in their own home (with or without assistance), in a relative's home or in a retirement village or sheltered accomodation but excludes participants living in nursing or care homes or residential care.

Facors used to define an individual as 'at risk' of institutionalisation will include frailty, as well as other factors that increase the risk of future functional decline or nursing home admission, such as recent hospital admission (Arnau 2016), baseline functional status (De Saint-Hubert 2009), or social isolation (Hajek 2015).

### Types of interventions

We will include trials that compare CGA meeting the following criteria with usual care.

- Delivered by a healthcare professional with gerontological expertise. This includes a geriatrician, specialist nurse or therapist with gerontological expertise.
- Used to inform a holistic care plan.
- A single assessment or multiple visits.
- Delivered in a community setting.

Traditionally CGA requires a minimum number of disciplines to be involved within the team (Ellis 2011). Given the community-based nature of the intervention involved in this Cochrane Review, one healthcare professional with an expertise in Geriatric Medicine, and therefore multidisciplinary work and links, will be sufficient.

### Types of outcome measures

#### Primary outcomes

- Death.
- Nursing home admission, i.e. new admission to full-time residential care during study follow-up period.
- Unplanned healthcare utilisation. This includes unscheduled GP visits, emergency department attendance and acute hospital admission.
- Serious adverse events.

#### Secondary outcomes

- Change in function (decline/improvement). Acceptable measures of function include the Barthel Index and Instrumental Activities of Daily Living Scale (IADL).
- Quality of life/well-being. Acceptable measures of quality of life include the Quality of Life Scale (QOLS), Older People's Quality of Life Questionnaire (OPQOL), World Health Organisation Quality of Life Questionnaire (WHOQOL), Control, Autonomy, Satisfaction, Pleasure - 19 items (CASP-19).

It is possible that investigators will use different tools to assess the same outcomes across the studies we identify. When this is the case, we will reach a consensus decision as to whether it is feasible to pool results, base don the characteristics of the outcome, as well as the tool used to measure it, and we will report this in the review. Reporting of the outcomes listed here will not be an inclusion criterion for the review and we will include studies regardless of the assessed outcomes.

## Search methods for identification of studies

### Electronic searches

The Information Specialist (IS) of the Cochrane Effective Practice and Organisation of Care (EPOC) Group will develop the search strategies in consultation with the review authors. We will search the Cochrane Database of Systematic Reviews (CDSR) and the Database of Abstracts of Reviews of Effects (DARE) for related systematic reviews.
We will search the following databases (from inception) for primary studies.

- The Cochrane Central Register of Controlled Trials (CENTRAL), including the Cochrane EPOC Group Specialised Register.
- MEDLINE, 1946 to present, In-Process and other non-indexed citations, OvidSP.
- Embase, 1974 to present, OvidSP.
- CINAHL (Cumulative Index to Nursing and Allied Health Literature), 1980 to present, EbscoHost.

Search strategies are comprised of keywords and controlled vocabulary terms. We will not apply language limits. We will search all databases from inception to the date of search.
We will use a modified version of the Cochrane Highly Sensitive Search Strategy (sensitivity- and precision-maximizing version - 2008 revision), per Chapter 6 of the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011a), to identify randomised trials. See Appendix 1 for the MEDLINE search strategy, which we will adapt to other databases.

### Searching other resources

#### Trial registries

- World Health Organization (WHO) International Clinical Trials Registry Platform (ICTRP): http://www.who.int/ictrp/en/
- ClinicalTrials.gov, US National Institutes of Health (NIH): http://clinicaltrials.gov/
- McMaster Ageing Portal: www.mcmasteroptimalaging.org/

#### Grey literature

We will conduct a grey literature search of the following sources to identify studies not indexed in the databases listed above.

- OpenGrey: www.opengrey.eu/
- Grey Literature Report (New York Academy of Medicine): www.greylit.org/
- Agency for Healthcare Research and Quality (AHRQ): www.ahrq.gov/
- Joanna Briggs Institute: http://joannabriggs.org
- National Institute for Health and Clinical Excellence (NICE): www.nice.org.uk/

We will also review reference lists of all included studies and relevant systematic reviews for additional potentially eligible primary studies; contact authors of included studies and reviews to clarify reported published information and to seek unpublished results/data; contact researchers with expertise relevant to the review topic/EPOC interventions; conduct cited reference searches for all included studies in ISI Web of Knowledge; and screen individual journals and conference proceedings (e.g. handsearch).
We will provide all strategies we use, including a list of sources screened and relevant reviews/primary studies reviewed, in the Appendices section of the review.

## Data collection and analysis

### Selection of studies

We will download all titles and abstracts retrieved by electronic searching to a reference management database and will remove duplicates. Two review authors (RB and AM) will independently screen titles and abstracts for inclusion. We will retrieve the full-text study reports/publications. Two review authors (RB and AM) will independently screen the full texts and identify studies for inclusion, and will identify and record reasons for exclusion of the ineligible studies. We will resolve any disagreement through discussion or, if required, we will consult a third review author (DR). We will list any studies that initially appear to meet the inclusion criteria but that we later exclude, and their reasons for exclusion, in the 'Characteristics of excluded studies' table. We will collate multiple reports of the same study so that each study rather than each report is the unit of interest in the review. We will also provide any information we can obtain about ongoing studies. We will record the selection process in sufficient detail to complete a PRISMA flow diagram (Liberati 2009), and 'Characteristics of excluded studies' table.

### Data extraction and management

We will use a standard data collection form adapted from the EPOC data collection form, described in the EPOC-specific resources for review authors (EPOC 2015a), for study characteristics and outcome data that we will pilot on at least one included study in the review. Two review authors (RB and AM) will independently extract the following study characteristics from the included studies.

- Methods: study design, number of study centres and location, study setting, withdrawals, date of study, follow-up.
- Participants: number, mean age, age range, gender, severity of condition, diagnostic criteria, inclusion criteria, exclusion criteria, other relevant characteristics.
- Interventions: intervention components, comparison, fidelity assessment.
- Outcomes: main and other outcomes specified and collected, time points reported.

- Notes: funding for trial, notable conflicts of interest of trial authors, ethical approval.

Two review authors (RB and AM) will independently extract outcome data from included studies. If an included study reports outcome data in an unusable way, we will note this in the 'Characteristics of included studies' table. We will resolve disagreements in extracted data by consensus or by involving a third review author (DR) according to the *Cochrane Handbook for Systematic Reviews of Interventions*, 7.6.5 (Higgins 2011b).

### Assessment of risk of bias in included studies

Two review authors (RB and AM) will independently assess the risk of bias for each included study using the criteria outlined in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011c). We will resolve any disagreement by discussion or by involving a third review author (DR). We will assess the risk of bias according to the following domains.

- Random sequence generation.
- Allocation concealment.
- Blinding of participants and personnel.
- Blinding of outcome assessment.
- Incomplete outcome data.
- Selective outcome reporting.
- Baseline outcomes measurement.
- Baseline characteristics.
- Other bias.

We will judge each potential source of bias as either high, low or unclear and we will provide a quote from the study report, together with a justification for our judgment, in the 'Risk of bias' tables. We will summarise the 'Risk of bias' judgements across different studies for each of the domains listed. We will consider blinding separately for different key outcomes where necessary (e.g. for unblinded outcome assessment, risk of bias for all-cause mortality may be very different than for a patient reported pain scale). Where information on risk of bias relates to unpublished data or correspondence with a trial author, we will note this in the 'Risk of bias' table. We will not exclude studies on the basis of their risk of bias, but we will clearly report the risk of bias when we present the results of the studies.
When we consider treatment effects, we will take into account the risk of bias for the studies that contribute to that outcome.
As we will include cluster randomised trials, we will consider the following additional biases.

- Recruitment bias.
- Baseline imbalance.
- Loss of clusters.
- Incorrect analysis.
- Compatibility with individual randomised trials.

### Assessment of bias in conducting the systematic review

We will conduct the review according to this published protocol and will report any deviations from it in the 'Differences between protocol and review' section of the review.

### Measures of treatment effect

We will estimate the effect of the intervention using the relative risk for dichotomous data, together with the appropriate associated 95% confidence interval (CI) and mean difference or standardised mean difference (SMD) for continuous data, together with the 95% appropriate associated CI. We will ensure that an increase in scores for continuous outcomes can be interpreted in the same way for each outcome, explain the direction to the reader and report where we reversed the directions if this was necessary.
If the included studies took the measures of treatment effect at baseline and follow-up, then we will use a change score. We will apply a random-effects meta-analysis as there will likely be heterogeneity in the selected studies. Where the $I^2$ statistic value suggests otherwise, we may use a fixed-effect model. As per Section 9.2 of the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011d), we will use SMD values throughout for consistency.

### Unit of analysis issues

We will include cluster randomised trials in the review. We will attempt to obtain a direct estimate of the required effect measure from the cluster randomised trials (e.g. an odds ratio with CI) if the analysis properly accounts for the cluster design. If cluster RCTs do not analyse the data appropriately for the cluster design, we will first contact the study authors to determine if they can conduct the appropriately adjusted analyses. If this is not possible, then we will apply a design effect using a suitable intra-class correlation derived from studies that included this information. We will base the methods we use to include cluster randomised trials on guidance from the *Cochrane Handbook for Systematic Reviews* and will describe these methods, including where we make adjustments to correct inappropriate applied analyses (Higgins 2011d).

### Dealing with missing data

If data is missing, we will contact the study authors to obtain missing data. If it is not possible to retrieve complete data, we will report this 'Risk of bias' assessment and address missing outcomes and summary data as a source of bias in the data analyses. We will contact study investigators in order to verify key study characteristics and obtain missing outcome data where possible (e.g. when we identify a study as an abstract only).
If standard deviation (SD) values are missing we will use any other available information (CIs, standard errors) to derive SD values.

If this information is not available, we will contact the study authors for the missing information. If we are unable to obtain any information, we will impute the SD values using the available information.

As per the guidance in Chapter 16 of the *Cochrane Handbook for Systematic Reviews of Interventions*, we will assume that missing data is missing at random (Higgins 2011e). We will use all other available data when we impute missing data.

### Assessment of heterogeneity

If we find a sufficient number of studies (at least five) we will conduct a meta-analysis. We will use the $I^2$ statistic value to measure heterogeneity among the trials in each analysis. If we identify significant heterogeneity, i.e. $I^2$ values greater than 75% (Higgins 2003), we will explore it by prespecified subgroup analysis (Higgins 2011d).

### Assessment of reporting biases

We will attempt to contact study authors and ask them to provide missing outcome data. Where this is not possible and we consider the missing data to introduce serious bias, we will explore the impact of including such studies in the overall assessment of results by a sensitivity analysis**.** If we are able to pool more than 10 trials, we will create and examine a funnel plot to explore possible publication biases, and will interpret the results with caution (Sterne 2011).

### Data synthesis

We will undertake meta-analyses only where this is meaningful i.e. if the treatments, participants and the underlying clinical question are similar enough for pooling to make sense. A common way that study authors indicate they have skewed data is by reporting medians and interquartile ranges. When we encounter this we will note that the data is skewed and consider the implications of this. Where multiple trial arms are reported in a single trial, we will include only the relevant trial arms. If we must enter two comparisons (e.g. intervention A versus usual care and intervention B versus usual care) into the same meta-analysis, we will halve the control group to avoid double counting.

### 'Summary of findings' table

We will summarise the findings of the main intervention comparison for the study outcomes (death, nursing home admission, unplanned healthcare utilisation, serious adverse advents, change in function, quality of life/well-being) in a 'Summary of findings' table to draw conclusions about the certainty of the evidence within the text of the review.

Two review authors will independently assess the certainty of the evidence (high, moderate, low or very low) using the five GRADE considerations (study limitations, consistency of effect, imprecision, indirectness and publication bias). We will use methods and recommendations described in Section 8.5 and Chapter 12 of the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011c; Higgins 2011f), and the Cochrane EPOC worksheets (EPOC 2015b). We will use GRADEpro Guideline Development Tool (GDT) software (GRADEpro GDT 2014). We will resolve disagreements on the assessments of the certainty of the evidence by discussion. We will provide justification for our decisions to downgrade or upgrade the certainty of the evidence using footnotes in the 'Summary of findings' table, and we will make comments to aid readers' understanding of the review where necessary. We will use plain language statements to report these findings in the review.

We will consider whether there is any additional outcome information that we were unable to incorporate into the meta-analyses. We will note this in the comments and state if it supports or contradicts the information from the meta-analyses. If it is not possible to meta-analyse the data, we will summarise the results in the text.

### Subgroup analysis and investigation of heterogeneity

We plan to perform the following subgroup analyses.

- CGA alone vs CGA with additional subsequent structured intervention: we plan to analyse this subgroup as some studies identified on initial review involve CGA, with a subsequent defined intervention, which may take the form of an exercise class, day hospital attendance etc. We plan to compare this to CGA alone, which will in certain circumstances also dictate further interventions, but these will be more heterogeneous, wide-ranging and not predefined. We feel it is important to do this subgroup analysis as the latter is more likely to reflect everyday practice by geriatricians in the community. It is likely that CGA with interventions/resources that are not predefined but are tailored to the specific patient would be more beneficial but this is dependant on the ability of that patient to access these specific resources.
- Single assessment vs multiple visits: we traditionally think of CGA in terms of an initial once-off assessment visit with subsequent prescribed contact with specific healthcare providers, such as therapists or social workers. However initial review of the literature has highlighted that in a community setting, multiple visits (by the healthcare professional delivering CGA) at different time-points may also be employed. One would expect that the latter would be more beneficial allowing for the extra cost/manpower involved and we wish to test this theory.

We will use the following outcomes in our subgroup analyses.

- Death.
- Nursing home admission.
- Healthcare utilisation.
- Functional decline.

In addition, we will consider the socioeconomic status, gender and age subgroups, primarily as covariates with analyses adjusted accordingly. We may consider age as a separate subgroup that focuses on the 'oldest old', e.g. those aged over 75 years.
If sufficient studies are available we will conduct a meta-regression. In any case, we will conduct tests for interaction for subgroup analysis.

### Sensitivity analysis

We will apply the Cochrane 'Risk of bias' tool and we will include studies that we identify as at low risk of bias for randomisation, concealment and blinding in the sensitivity analysis (Higgins 2011d).
We will perform sensitivity analysis defined a priori to assess the robustness of our conclusions and explore its impact on effect sizes. This will involve the following.

- Restriction of the analysis to published studies.
- Restriction of the analysis to studies at low risk of bias.
- Imputation of missing data.

If we need to adjust any studies for unit of analysis errors, we will perform sensitivity analyses to test different assumptions about the intracluster correlation coefficient (ICC), as recommended in Chapter 9 of the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011d)

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* *Indicates the major publication for the study*

# APPENDICES

## Appendix 1. MEDLINE search strategy

MEDLINE (OVID)
Epub Ahead of Print, In-Process & Other Non-Indexed Citations, Ovid MEDLINE Daily and Ovid MEDLINE 1946 to Present

| No. | Search terms |
|---|---|
| 1 | geriatric assessment/ |
| 2 | health services for the aged/ |
| 3 | ((geriatric? or elder* or old age or old* adult? or senior? or old* patient?) adj5 (assess* or evaluat* or consult*)).ti,ab |
| 4 | health status/ |
| 5 | exp aged/ |
| 6 | 4 and 5 |
| 7 | or/1-3,6 |
| 8 | primary health care/ |
| 9 | physicians, family/ |
| 10 | physicians, primary care/ |
| 11 | general practice/ |

(*Continued*)

| | |
|---|---|
| 12 | general practitioners/ |
| 13 | family practice/ |
| 14 | practice patterns, physicians'/ |
| 15 | ambulatory care/ |
| 16 | outpatient clinics, hospital/ |
| 17 | community health centers/ |
| 18 | exp community health services/ |
| 19 | community health planning/ |
| 20 | community-based participatory research/ |
| 21 | independent living/ |
| 22 | day care, medical/ |
| 23 | residential facilities/ |
| 24 | assisted living facilities/ |
| 25 | group homes/ |
| 26 | halfway houses/ |
| 27 | homes for the aged/ |
| 28 | exp nursing homes/ |
| 29 | (communit* adj3 (care or healthcare or service? or network? or based or initiative* or intervention* or schem* or participat* or project* or program* or activit* or partnership* or action or strategy*)).ti,ab |
| 30 | (primary adj2 (care or healthcare)).ti,ab. |
| 31 | (family practi* or family doctor* or family physician* or gp* or general practi*).ti,ab |
| 32 | (group? adj (home? or living)).ti,ab. |
| 33 | ((home or domicil*) adj3 (care or healthcare or nurs* or rehabilit* or service or services or treatment? or therapy or therapies or therapist? or visiting or visit?)).ti,ab |
| 34 | (residential adj3 (care or healthcare or facilit*)).ti,ab. |

(*Continued*)

| | |
|---|---|
| 35 | (day hospital? or ((adult? or elder* or geriatric?) adj2 (day care or daycare))).ti,ab |
| 36 | halfway hous*.ti,ab. |
| 37 | respite care.ti,ab. |
| 38 | or/8-37 |
| 39 | 7 and 38 |
| 40 | exp randomized controlled trial/ |
| 41 | controlled clinical trial.pt. |
| 42 | randomi#ed.ti,ab. |
| 43 | placebo.ab. |
| 44 | randomly.ti,ab. |
| 45 | clinical trials as topic.sh. |
| 46 | trial.ti. |
| 47 | or/40-46 |
| 48 | exp animals/ not humans/ |
| 49 | 47 not 48 |
| 50 | 39 and 49 |

## CONTRIBUTIONS OF AUTHORS

David Robinson (DR) and Robert Briggs (RB) conceived and wrote the protocol.

DR, RB, Desmond O'Neill (DON) Anna McDonough (AM) and Kathleen Bennett (KB) designed the protocol.

KB provided statistical advice.

DR, RB and AM coordinated the protocol.

RB designed the search strategies.

Graham Ellis (GE), DON and KB provided general advice on the protocol.

DR, DON and GE performed previous work that was the foundation of this Cochrane Review.

Secured funding for the protocol: N/A

## DECLARATIONS OF INTEREST

RB has no known conflicts of interest.

AM has no known conflicts of interest.

KB has no known conflicts of interest.

DON has no known conflicts of interest.

GE has no known conflicts of interest.

DR has no known conflicts of interest.

## SOURCES OF SUPPORT

### Internal sources

- No sources of support, Other.

### External sources

- No sources of support, Other.

## NOTES

This protocol is based on standard text and guidance provided by the Cochrane EPOC Group.